

Remarks/Arguments

The Examiner has issued a final Office Action, citing the following grounds for rejection:

- (1) Claims 3-4 are rejected under 35USC§112 first paragraph as lacking enablement.
- (2) Claims 1-5 are rejected under 35USC§102(e) as anticipated by Jiao (US Patent 6,812,234).
- (3) Claims 1-5 are rejected under 35USC§103(a) as obvious over Jiao (WO 03/093266).
- (4) Claims 1 and 5 are provisionally rejected for obviousness-type double patenting over Claims 3 and 15 of copending Application No. 10/577,587. The patent application has been granted and is now US Patent 7,361,765. The previously cited claims are Claims 2 and 7 of the patent.

Amendments

Claims 2-4 have been canceled. Claims 1 and 5 are pending after the above amendment is entered.

Claims 1 and 5 are directed to the succinate salt of the specific compound of formula 1 and a pharmaceutical composition comprising the succinate salt.

Claims 1 and 5 are rejected under 35USC§102(e) as anticipated by the Jiao '234 US Patent and under 35USC§103(a) as obvious over Jiao (WO 03/093266). The rejection over the Jiao WO '266 publication is incorrect. WO 03/093266 was published on November 13, 2003. The publication date is after the priority date of the instant application (October 27, 2003), and it therefore is not prior art for 102(a) purposes. The Jiao '234 US Patent and the Jiao WO '266 publication both disclose the compound of formula I, but not its succinate salt. They both can be cited only under 35 USC§102(e), and since they and the instant application are commonly assigned, they can only be cited as references for novelty, and not obviousness.

For clarification, the instant patent application is assigned to Merck & Co., Inc. The Jiao WO '266 publication and the Jiao '234 US Patent are assigned to both Merck & Co., Inc. and Merck Sharp & Dohme Ltd. Because Merck Sharp & Dohme Ltd. is a wholly owned subsidiary of Merck & Co., Inc., all of the patents and patent applications described above are wholly owned by Merck & Co., Inc.

For completeness, another related PCT application, WO 2003/092586, was filed and published on the same dates as the WO '266 publication. All three documents disclose the compound of Formula I in the current application, but none discloses the succinate salt. These can all be cited only for purposes of novelty. These all have descriptions of the compound of formula 1 and salts of the compound. The most explicit description is that in Claim 29 of the Jiao '234 US Patent, which shows the structure of the compound of formula 1 in the instant application, and claims a list of salts of the compound that can be made from a list of 31 acids, including succinic acid. The list does not explicitly disclose or suggest the salt that is isolated and claimed in the instant application. There is no information in the patent that specifically suggests the succinate salt to one of ordinary skill in the art. The two cited references cannot be cited as references for obviousness, and they are not novelty destroying references. They therefore should be withdrawn.

The rejections under 35 USC§112, first paragraph are moot because Claims 2-4 have been canceled.

The examiner has also rejected Claims 1 and 5 of this application over the Claims of US Application 10/577,587, now US Patent 7,361,765 under the doctrine of obviousness double patenting. Claim 5 of the '765 patent claims a process for making the succinate salt claimed in the instant application. A terminal disclaimer is included with this response to obviate this rejection, thereby expediting allowance of the claims.

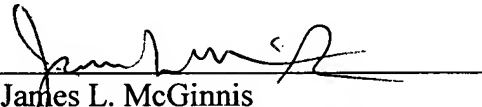
Conclusion

The references cited by the examiner are suitable as references only for novelty under 35USC§102(e). The cited references do not disclose the specific salt that is claimed in the instant application. They merely provide a list of 31 acids that may be used to make salts.

The terminal disclaimer enclosed herewith removes the obviousness-type double patenting rejection.

The claims are therefore in condition for allowance. Such action is earnestly solicited. No fee is believed due if the claims are allowed. If a fee is necessary to consider this response it may be charged to Merck Deposit Account 13-2755. If the examiner has any questions about this response, the examiner is requested to telephone the undersigned attorney.

Respectfully submitted,

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